MAR 2 8 2005

IFW 644\$

PATENT Attorney Docket No. MEE-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Miller et al.

SERIAL NO.:

09/780,142

GROUP NO.:

1644

FILING DATE:

February 9, 2001

EXAMINER:

Huynh, P.

TITLE:

METHODS AND COMPOSITIONS FOR TREATING CONDITIONS

OF THE EYE

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of March, 2005.

Carrah M. Malone

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

- 1. Transmittal Form (1 page);
- 2. Fee Transmittal (1 page);
- 3. Check in the amount of \$180.00;
- 4. Supplemental Information Disclosure Statement (2 pages),
- 5. Form PTO 1449 (4 pages);
- 6. Copies of cited references B8-B11 and C119-C169; and
- 7. Return Receipt Postcard

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7	4		Application	Serial Number		09/780,142			
MAR 2 8 2005 Fi						February 9, 2001			
First Nam				Inventor	Miller				
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`	•		Examiner N	ame		Huynh, P.			
	FORM		Attorney Do	cket No.		MEE-002			
			Patent No.	Patent No.		Not applicable			
			Issue Date			Not applicable			
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⊠ F	ee Transmittal Form			to File Missing	Ι	Notice of Appeal to Board			
			Parts of Applic	_		of Patent Appeals and Interferences			
	Check AttachedCopy of FeeTransmittal Form		Formal Drawin	ng(s)		Appeal Brief (in triplicate)			
	Amendment/Response	Request For Continued Examination (RCE)				Status Inquiry			
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	Affidavits/declaration(s) Letter to Official Draftsperson including Drawings		Power of Attor (Revocation of	•	Ø	-			
	[Total Sheets]		Terminal Discl	aimer		Certificate of Facsimile Transmission under 37 C.F.R. 1.8			
	Petition for Extension of Time			r Utility or Design		Additional Enclosure(s) (please identify below)			
Supplemental Information Disclosure Statement (2 pgs.) Form PTO-1449			Small Entity Statement						
	Copies of IDS Citations (B8-B11 and C119-C169)		CD(s) for large program	table or computer					
	Certified Copy of Priority		Amendment A	fter Allowance					
	Document(s)		Request for Ce	rtificate of					
	Sequence Listing submission Paper Copy/CD Computer Readable Copy Statement verifying	Correction	of Correction (in						
	identity of above								
CORI	RESPONDENCE ADDRESS			SIGNATURE BL	oc	K			
Direct all correspondence to: Patent Administrator Goodwin Procter LLP Exchange Place Boston, MA 02109 Tel. No.: (617) 570-1000 Fax No.: (617) 523-1231 Customer No. 051414			Date: March 24 , 200 Reg. No. 38,678 Tel. No.: (617) 570 Fax No.: (617) 523	-129	Goodwin Procter LLP Exchange Place				
				(1)		Boston, MA 02109			

FEE TRANSMITTAL
FYS 2005
MAR 2 8 2005

	Complete if Known
Application Serial Number	09/780,142
Filing Date	February 9, 2001
First Named Inventor	Miller
Group Art Unit	1644
Examiner Name	Huynh, P.
Attorney Docket No.	MEE-002

THOD OF PAYMENT			FEE CALCULATION (continued)	
1. A Payment Enclosed:	3. ADD	ITIONAL	FEES	
Check Money Order Other	Large Entity	Small Entity		
2. The Commissioner is hereby authorized to credit	Fee	Fee	Fee Description	Fee Paid
or charge any fee indicated below for this submission to Deposit Account No. 07-1700.	(\$)	(\$)	•	
Required Fees (copy of this sheet enclosed).	130	65	Surcharge - late filing fee or oath	
Additional fee required under 37 CFR 1.16 and 1.17.	50	25	Surcharge - late provisional filing fee or cover	
			sheet	
Overpayment Credit.	130	130	Non-English specification	
3. Applicant claims small entity status.	2,520	2,520	Request for ex parte reexamination	
FEE CALCULATION	120	60	Extension for reply within first month	
1. FILING/SEARCH/EXAM/SIZE FEES	450	225	Extension for reply within second month	
Large Entity	1020	510	Extension for reply within third month	
Fee (\$) Fee Description Fee Paid	1590	795	Extension for reply within fourth month	
	2160	1080	Extension for reply within fifth month	
300 Utility filing fee	500	250	Notice of Appeal	
500 Utility search fee	500	250	Filing a brief in support of an appeal	
200 Utility exam fee	1000	500	Request for oral hearing	
Utility size fee (each add'l 50 pgs. over 100)	400	400	Petitions to the Commissioner (Gp. 1)	
200 Design filing fee	200	200	Petitions to the Commissioner (Gp. II)	
100 Design search fee	130	130	Petitions to the Commissioner (Gp. III)	100.00
Design exam fee	180	180	Submission of Information Disclosure	180.00
Design size fee (each add'l 50 pgs. over 100)	700	205	Statement Eiling a submission ofter final	
	790	395	Filing a submission after final rejection (37 CFR 1.129(a))	
Number Number Rate Amount	790	395	For each additional invention to be	
Filed Extra	///	373	examined (37 CFR 1.129(b))	
Total Claims $-20 = x \$ 50.00 =$	100	100	Certificate of Correction for	
		100	applicant's error	;
Independent	130	65	Submission of Terminal Disclaimer	
Claims $-3 = x $200.00 =$	Other fee ((Specify)		
	Other fee ((Specify)		
☐ Multiple Dependent Claim(s), if any \$360.00 =				
TOTAL:				
SMALL ENTITY DISCOUNT:	4			
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Direct all correspondence to:		•	Respectfully submitted,	
Patent Administrator	Date: Marc	ch 24. 200	05 DA-tm/	
Goodwin Procter LLP	Reg. No.:		Duncan A. Greenhalgh	
Exchange Place	T -	(617) 570-		
Boston, MA 02109	1	(617) 523-	•	
Tel. No.: (617) 570-1000		, , ,	Exchange Place	
Fax No.: (617) 523-1231			Boston, MA 02109	
Customer No. 051414				



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Huynh, Phuong N.

TITLE:

METHODS AND COMPOSITIONS FOR TREATING CONDITIONS

OF THE EYE

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with 37 C.F.R. 1.98(a)(2), only copies of the foreign patent documents and non-patent publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

	(1)	within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) month of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or	
\boxtimes	(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and	
		the requisite Statement is below, OR	00000052
		the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or	03/29/2005 LWONDIMI

Supplemental Information Disclosure Statement Serial No. 09/780,142 Page 2 of 2

(3)	after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND				
	the requisite Statement is below, AND				
	the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.				

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R.

 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Date: March 24, 2005 Reg. No. 38,678

Tel. No.: (617) 570-1299

Fax No.: (617) 523-1231

VER 11/03

Respectfully submitted

Duncan A. Greenhalgh Attorney for Applicants Goodwin Procter LLP

Exchange Place

Boston, Massachusetts 02109

Customer No. 051414

EXRM PTO – 1449 SEATEMENT

MAR 2 8 2005 SUPPLEMENTAL INFORMATION DISCLOSURE

ATTORNEY DOCKET NO.: MEE-002

APPLICANTS: Miller et al.

SERIAL NO.: 09/780,142

FILING DATE: February 9, 2001

EXAMINER: Huynh, P. GROUP: 16					44						
\ -			U.S	S. PATENT DO	CUMENT	S					
EXAM. INIT.		DOCUMENT DAT NUMBER		NAME			CLASS	SU CL	B LASS	FILING DATE IF APPROPRIATE	
	A9	2002/0049247	4/25/2002	Chen							
·	A10	2003/0171320	9/11/2003	Guyer et al.	•						
	A11	2004/0167091	8/26/2004	Guyer et al.						<u> </u>	
	A12	2005/0043220	2/24/2005	Guyer et al.				·			
	A13	6,270,749	8/7/2001	Blumenkranz	et al.						
	_		FORE	IGN PATENT	DOCUME	NTS					
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLAS		FILING DATE		'RACT	ENGLISH LANG (Y/N)
	B8	WO 97/05127	2/13/1997								
	B9	WO 00/40089	7/13/2000								
	B10	WO 01/58240	8/16/2001								
	B11	WO 03/039404	5/15/2003								
•			OTHER A	RT, JOURNA	L ARTICLE	S, ETC	•				- 1 - 1 - 1 - 1
EXAM. INIT.	ОТНЕ	R DOCUMENTS:	(Including A	uthor, Title, D	ate, Releva	nt Page	s, Place of	f Pub	lication)	
	C119	"A Clinical Trial to Evaluate the Effect of an Experimental Compound on Reducing the Number of Retreatments Required in Photodynamic Therapy (PDT) with Visudyne TM ," Alcon web site, http://www.alconlabs.com/us/co/c-00-07study.ihtml (printed April 4, 2003).									
	C120	Adamis, "Looking Forward: Ocular Biochemical Warfare - The VEGF Attack," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).									
	C121	Behling et al., "Adeno-associated Delivery of TIMP-3 Inhibits Experimental Choroidal Neovascularization," Invest. Ophthalmol Vis Sci. 44: E-Abstract 1425 (2003).									
	C122	Blumenkranz et al., "Verteporfin therapy for subfoveal choroidal neovascularization in age-related macular degeneration: three-year results of an open-label extension of 2 randomized clinical trialsTAP Report no. 5," <u>Arch Ophthalmol.</u> 120(10):1307-14 (Oct. 2002).									
	C123										
	C124	Campochiaro et al., "The pathogenesis of choroidal neovascularization in patients with age-related macular degeneration," Molecular Vision 5: 34-8 (Nov. 3, 1999).									
	C125	Ciulla <i>et al.</i> , "Age 43 (2): 134-46 (19		ular Degenerati	ion: A Revi	ew of E	xperiment	al Tre	atments	," <u>Surv.</u>	Ophthalmo
	C126	Corjay et al., "alp Neovascularizatio	ha _v beta ₃ , alpha		-		-	_	imental	Choroid	al
EXAMIN	ER				DATE (CONSII	DERED			-	

FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-002

APPLICANTS: Miller et al.

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FILING DATE: February 9, 2001

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		EXAMINER: Huynh, P. GROUP: 1644						
		OTHER ART, JOURNAL ARTICLES, ETC.						
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	C127	Csaky, K., "Anti-vascular endothelial growth factor therapy for neovascular age-related macular degeneration: promises and pitfalls (Comment)," Ophthalmology 110(5):879-81 (May 2003).						
	C128	Dahlin et al., "Design of a Specialized Cannula for Poseterior Juxtascleral Delivery of Anecortave Acetate to the Retina for Treatment CNV Associated with Age-Related Macular Degeneration," Invest. Ophthalmol Vis Sci. 44: E-Abstract 5036 (2003).						
	C129	Danis, "Pharmacotherapy for AMD: The Role of Intravitreal Steroids and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).						
	C130	de Juan, "Surgery for AMD: Limited Translocation in the Era of Photodynamic Therapy," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).						
	C131	Eyetech Study Group, "Anti-vascular endothelial growth factor therapy for subfoveal choroidal neovascularization secondary to age-related macular degeneration: phase II study results," Ophthalmology 110(5):979-86 (May 2003).						
	C132	Gallemore et al., "AMD Treatment Update: Along with Visudyne and TTT, injectable anti-angiogenesis agents are on the forefront of current research," Ophthalmology Management, 69-72 (March 2003).						
	C133	Gauthier et al., "Safety and Efficacy of Intravitreal Injection of rhuFab V2, an Anti-vascular Endothelial Growth Factor (VEGF) in Combination With Verteporfin PDT on Experimental Choroidal Neovascularization," ARVO Poster.						
	C134	Gauthier et al., "Safety and Efficacy of Intravitreal Injection of rhuFab VEGF in Combination With Verteporfin PDT on Experimental Choroidal Neovascularization," ARVO, The Association for Research in Vision and Ophthalmology (Oasis, Online Abstract Submission and Invention System, Program Planner, Presentation # 566).						
	C135	Granville et al., "Fas ligand and TRAIL augment the effect of photodynamic therapy on the induction of apoptosis in JURKAT cells," International Immunopharmacolgy 1: 1831-40 (2001).						
	C136	Guyer, D.R., "Pharmacotherapy for AMD: VEGF Inhibitors and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).						
	C137	Haimovici et al., "Localization of Lipoprotein-delivered benzoporphyrin derivative in the rabbit eye," <u>Curr.</u> Eye Res. 16(2):83-90 (1997).						
	C138	Heier et al., "rhuFAB V2 (an Anti-VEGF Antibody Fragment) in Neovascular AMD: Safety and Tolerability of Multiple Intravitreal Injections - Preliminary Data from a Single Center," <u>ARVO Poster</u> .						
	C139	Husain et al., "Effects of Photodynamic Therapy Using Verteporfin on Experimental Choroidal Neovasculaturization and Normal Retina and Choroid up to 7 Weeks after Treatment," <u>Invest. Ophthalmol Vis Sci.</u> 40(10): 2322-31 (1999).						
	C140	Husain et al., Photodynamic therapy and digital angiography of experimental iris neovascularization using liposomal benzoporphyrin derivative," Ophthalmology 104(8):1242-50 (Aug. 1997).						
	C141	International Search Report for PCT/US01/04231 completed on November 23, 2001						
	C142	Kaiser et al., "Five-Year Results of Verteporfin Therapy for Subfoveal CNV Due to AMD: Third Year of an Open-label Extension of the TAP Investigation," <u>Invest. Ophthalmol Vis Sci.</u> 44: E-Abstract 1099 (2003).						
	C143	Kitchen et al., "Anecortave Acetate Monotherapy for the Treatment of Occult and Minimally Classic Choroidal Neovascularization in Age-related Macular Degeneration," <u>Invest. Ophthalmol Vis Sci.</u> 44: E-Abstract 5039 (2003).						
EXAMIN	ER	DATE CONSIDERED						
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

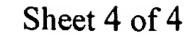
ATTORNEY DOCKET NO.: MEE-002

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EXAMINER: Huynh, P. **GROUP: 1644** OTHER ART, JOURNAL ARTICLES, ETC. EXAM. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) INIT. Kliman et al., "Angiography and Photodynamic Therapy of Experimental Choroidal Neovascularization using C144 Phthalocyanine Dye," Invest. Ophthalmol. Vis. Sci. (Suppl.) 30(3): 371 (1989). Krzystolik et al., "Prevention of Experimental Choroidal Neovascularization With Intravitreal Anti-Vascular C145 Endothelial Growth Factor Antibody Fragment," Arch. Ophthalomol. 120(2): 338-346 (2002). Lai et al., "Suppression of Choroidal Neovascularization by Adeno-associated Virus Vector Expressing C146 Angiostatin," Investigative Ophthalmology & Visual Science 42 (10): 2401-2407 (2001). Leibowitz et al., "The Framingham Eye Study Monograph: An ophthalmological and epidemiological study of C147 cataract, glaucoma, diabetic retinopathy, macular degeneration, and visual acuity in a general population of 2631 adults," Survey of Ophthalmology, Supplement (May-June 1980). Miller, "Photodynamic Therapy for AMD: Expanded Indications," American Academy of Ophthalmology C148 Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002). Ngo et al., "Computational Complexity, Protein Structure Prediction, and Levinthal Paradox," Chapter 14 of C149 The Protein Folding and Tertiary Structure Prediction, Merz and LeGrand, Eds., Burkhauser Boston, 1994. Oleinick et al., "The role of apoptosis in response to photodynamic therapy: what, where, why, and how," C150 Photochem. Photobiol. Sci. 1: 1-21 (2002). Olsen et al., "An Evaluation of an Episcleral Anecortave Acetate Transscleral Drug Delivery System in Rhesus C151 Monkey," Invest. Ophthalmol Vis Sci. 44: E-Abstract 4213 (2003). Pasqualini et al., "Organ Targeting in Vivo using Phage display Peptide Libraries," Nature 380: 364-6 (1996). C152 Reinke et al., "Verteporfin photodynamic therapy retreatment of normal retina and choroid in the cynomolgus C153 monkey," Ophthalmology 106(10):1915-23 (Oct. 1999). Renno et al., "Expression of pigment epithelium-derived factor in experimental choroidal neovascularization," C154 Invest Ophthalmol Vis Sci. 43(5):1574-80 (May 2002). Renno et al., "Photodynamic therapy using Lu-Tex induces apoptosis in vitro, and its effect is potentiated by C155 angiostatin in retinal capillary endothelial cells," Invest Ophthalmol Vis Sci. 41(12):3963-71 (Nov 2000). Renno et al., "Photosensitizer delivery for photodynamic therapy of choroidal neovascularization. C156 Adv Drug Deliv Rev. 52(1):63-78 (Oct. 31, 2001) Review. Renno et al., "Selective photodynamic therapy by targeted verteporfin delivery to experimental choroidal C157 neovascularization mediated by a homing peptide to vascular endothelial growth factor receptor-2," Arch Ophthalmol. 122(7):1002-11 (July 2004). Schlingemann et al., "Role of vascular permeability factor/vascular endothelial growth factor in eye disease," C158 Br. J. Ophthalmol. 81: 501-12 (1997) Schmidt-Erfurth et al., "Photodynamic therapy with verteporfin for choroidal neovascularization caused by C159 age-related macular degeneration: results of retreatments in a phase 1 and 2 study," Arch Ophthalmol. 117(9):1177-87 (Sept. 1999). Erratum in: Arch Ophthalmol. 118(4):488 (April 2000). Sickenberg et al., "A preliminary study of photodynamic therapy using verteporfin for choroidal C160 neovascularization in pathologic myopia, ocular histoplasmosis syndrome, angioid streaks, and idiopathic causes." Arch Ophthalmol. 118(3):327-36 (March 2000). Slakter et al., "Ancortave Acetate Administered as a Posterior Juxtascleral Injection for Subfoveal CNV in C161 Age-Related Macular Degeneration (AMD-Climical Results)," Presentation at the Retina Congress 2002 Symposium (Sept. 8, 2002). **EXAMINER DATE CONSIDERED**



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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	C162	Slakter, "Pharmacotherapy for AMD: The Role of Periocular Steroids and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).						
"	Slakter et al., "Sub-Tenon's Administration of the Angiostatic Agent Anecortave Acetate in AMD Patients with Subfoveal Choroidal Neovascularization (CNV) - the Clinical Outcome," Invest. Ophthalmol Vis Sci. 44: E-Abstract 2909 (2002).							
	C164	Slakter et al., "Verteporfin With Altered (Delayed) Light in Occult CNV (VALIO) - Results of a Phase II Controlled Clinical Trial," Invest. Ophthalmol Vis Sci. 44: E-Abstract 1101 (2003).						
	Trese, "Treatment of Neovascularization in ROP: Pharmacological Agents and the ERTOP Study," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).							
. '	C166	Verma et al., "Gene therapy - Promises, problems and prospects," Nature 389: 239-42 (Sept. 1997).						
C167 Yaacobi <i>et al.</i> , "In-Vivo Studies with Trans-Scleral Anecortave Acetate Delivery Device De Choroidal Neovascularization in AMD," <u>Invest. Ophthalmol Vis Sci.</u> 44 : E-Abstract 4210 (2)								
	Zacks et al., "Caspase Activation in an Experimental Model of Retinal Detachment," <u>Investigative</u> <u>Ophthalmology & Visual Science</u> 44(3): 1262-7 (March 2002).							
	C169 Zacks et al., "Verteporfin Photodynamic Therapy in the Rat Model of Choroidal Neovascularization: Angiographic and Histologic Characterization," Investigative Ophthalmology & Visual Science 43 (0) (2002).							

EXAMINER